DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3003080243
CFN: 1125881

Food and Drug Administration
Baltimore District Office
Central Region
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Baltimore, MD 21215
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02-BLT-13

January 3, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Mosier, Sr. CEO
Pharmaceutical Distribution Systems
5171 Waterway Drive #217
Montclair, Virginia 22026

Dear Mr. Mosier,

The Food and Drug Administration inspected your drug repacking facility located at 8655 Cherry Lane, Laurel, Maryland, on November 15 to December 5, 2001. Our inspection found significant deviations from Current Good Manufacturing Practice (CGMP) Regulations, Title 21, Code of Federal Regulations (21 CFR), Part 211. Such deviations cause your drug products to be adulterated within the meaning of Section 501(a) (2) (B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in or the facilities or controls used for their manufacturing, processing, packing, storage, or holding are not in conformance with GMP regulations.

The deviations include, but are not limited to the following:

1. Failure to use a separate facility for the repackaging of penicillin products for human use (21 CFR 211.42). From April 16, through November 16, 2001, your firm repackaged at least [redacted] different lots of penicillin, in both tablet and capsule dosage forms, while concurrently repackaging over [redacted] different types of non-penicillin drug products. Both penicillin and non-penicillin drug products were repackaged in the same facility using the same equipment.

2. Failure to have completely separate air-handling systems for the repackaging operations of penicillin and non-penicillin drug products for human use (21 CFR 211.46). The same facility and air-handling system was used for the repackaging operations of both penicillin and non-penicillin drugs for human use from April 16 through November 16, 2001.

3. Failure to test non-penicillin drug products for the presence of penicillin when a reasonable possibility exists that non-penicillin drug products could have been exposed to cross-contamination with penicillin (21 CFR 211.176).

4. Failure to exercise appropriate controls over and to routinely calibrate, inspect, or check automatic, mechanical, or electronic equipment used in the manufacturing, processing, and packaging of a drug product according to a written program designed to assure proper performance (21 CFR 211.68) in that, the installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ), for th[redacted] was not performed.

5. Failure to establish written procedures (21 CFR 211.22, 211.67, 211.80, 211.100, 211.122, 211.166, and 211.198) for the following:

   a. The responsibilities and operations of the quality control unit;

   b. Stability testing program to assess the stability characteristics of drug products to determine the appropriate storage conditions and expiration dates for any of the products repackaged;

   c. The receipt, identification, storage, handling, sampling, testing, approval or rejection of components and drug product containers and closures, and for maintaining and recording the identity and quantity of each shipment for each lot of drug product containers and closures;

   d. The preparation of batch production records;

   e. The receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; preparation and printing of labels; examination and review of labels; disposition of rejected labeling; issuance of labeling; reconciliation of quantities of labeling issued, used and returned; destruction of unused labels bearing lot numbers; and the 100% visual inspection of labels hand applied to drug products;

   f. The monitoring of temperatures, humidity, and the air-handling system in the production area;

   g. The inspection, calibration, and monitoring of the production equipment;

   h. The handling of written and oral consumer complaints; and

   i. The training provided to employees for pre-production, production, and post-production operations performed at the firm.

6. Failure to establish adequate written procedures that provide sufficient detail to assure that drug products have the identity, strength, quality, and purity they purport or are represented to possess, in that:

a. The incoming bulk drug products procedure does not sufficiently describe each processing step for the receipt, identification, storage, handling, and approval or rejection of incoming bulk drug products (21 CFR 211.80). For example, this procedure states that the employee is to perform the examination of incoming bulk drug products, but provides no details as to how this is to be accomplished ;

b. The reserve sample procedure does not sufficiently describe in detail the storage method and storage location for reserve samples. The procedure also does not allow for at least twice the quantity necessary for all tests required, to determine whether the active ingredient meets its established specification (21 CFR 211.160(a));

c. The production area cleaning and maintenance procedure and production equipment cleaning and maintenance procedure does not sufficiently describe in detail any step in the cleaning or maintenance of the production area or of the production equipment (21 CFR 211.67). For example, your firm has four written procedures regarding the cleaning and maintenance of the production area and production equipment. However, the written procedures do not describe decontamination/cleaning solutions, decontamination/cleaning methods, or the preparation of cleaning and maintenance documentation to track these activities;

d. The employee sanitation procedure does not describe in sufficient detail methods that are to be used by employees to protect products from contamination (21 CFR 211.56). For example, employees were observed not wearing protective apparel that completely covered their head, face, and arms, while performing production operations; and

7. Failure to document the following:

a. The cleaning, sanitizing, and maintenance of walls, ceilings, and hard surfaces, in the production area (21 CFR 211.56).

b. The cleaning, sanitizing, and maintenance of the facility production equipment, including: the [redacted] and plastic storage totes used in the pre-production preparation process (21 CFR 211.67).

8. Failure to maintain adequate and complete batch production and distribution records (21 CFR 211.80, 211.180, 211.182, 211.188, and 211.196) in that:

a. Each step in the production process is not documented. For example, your firm was observed performing various examinations during the pre-production, production, and post-production processing of products. But none of these examinations were being documented;

b. Batch production records do not include:

   i. actual count for incoming bulk drug products or drug products remaining after repackaging:
   ii. identification of persons performing , supervising, or checking production operation steps;
   iii. inspection results for packaging and labeling area;
   iv. final drug product inspection results;
   v. complete labeling control records;
   vi. description of drug product containers and closures;
   vii. results of final visual examination at operation completion; and
   viii. date and signature for accuracy.

c. Information was incorrectly obliterated or white out was used, on 14 different dates;

d. Cleaning after each repackaging operation was not documented on seven different dates;

e. On April 16, 2001 and October 22, 2001, the same lot numbers were used for different repackaged products;

f. On July 3, 2001, 20 lot numbers were not accounted for on batch production records or cleaning logs;

g. On October 17, 2001, five lot numbers were not accounted for on batch production records; and

h. Lot numbers for repackaged drug products were missing in all distribution records between April 16, 2001and November 26, 2001.

The above is not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and on the Form FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions without further notice. These sanctions include, but are not limited to, seizure and/or injunction.

Please notify this office in a detailed written response within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations and to prevent recurrence. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

You should direct your response and questions to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215-3215, to the attention of Vinetta Howard-King, Compliance Officer. Ms. Howard-King can be contacted at telephone number (410) 779-5454 x 413.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Mr. John Mosier, Sr. CEO
Pharmaceutical Distribution systems, Inc.
8655 Cherry Lane
Laurel, MD 20702